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DATE : August 17, 2004 TIME: 7:15
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MESSAGE:

Please find enclosed a Supplemental Communication Regarding Examiners' Interview, Petition for a One-Month Extension of Time in connection with David M. Stern, et al., A Method to Prevent Accelerated Atherosclerosis Using (sRAGE) Soluble Receptor for Advanced Glycation Endproducts, U.S. Serial No. 08/905,709.

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Dkt. 0575/52876/JPW/AJM/AAB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : David M. Stern, et al.
U.S. Serial No.: 08/905,709 Examiner: Ruixiang Li
Filed : August 5, 1997 Group Art Unit: 1646
For : A METHOD TO PREVENT ACCELERATED
ATHEROSCLEROSIS USING (sRAGE) SOLUBLE RECEPTOR
FOR ADVANCED GLYCATION ENDPRODUCTS

1185 Avenue of the Americas
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August 17, 2004

VIA FACSIMILE

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Sir:

SUPPLEMENTAL COMMUNICATION REGARDING EXAMINER'S
INTERVIEW, PETITION FOR A ONE-MONTH EXTENSION OF TIME

This Supplemental Communication is submitted in connection with a November 12, 2003 Final Office Action issued by the United States Patent and Trademark Office and as agreed during a July 15, 2004 Examiner's Interview with Examiners Ruixiang Li and Brenda Brumback of the United States Patent and Trademark Office in connection with the above-identified application. A response to the November 12, 2003 Final Office Action was originally due February 12, 2003. Applicants filed an Amendment In Response on February 12, 2004. On March 9, 2004, an Advisory Action was issued by the United States Patent and Trademark Office. Applicants filed a Notice of Appeal on May 12, 2004. A brief on appeal was originally due

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July 17, 2004, based on the May 17, 2004 receipt by the United States Patent and Trademark Office of applicants' Notice of Appeal mailed May 12, 2004. Applicants hereby petition for a one-month extension of time in which to file a brief on appeal. The required fee for a one-month extension of time is FIFTY-FIVE DOLLARS (\$55.00) for a small entity, and authorization to charge this amount to Deposit Account No. 03-3125 is hereby given. With a one-month extension of time, a brief on appeal is now due August 17, 2004, and this Supplemental Communication is being timely filed.

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REMARKS

Claims 1-4, 8, 9, 15-18, 36, 37 and 46 are pending in the subject application. No claim has been added, canceled or amended herein. Accordingly, claims 1-4, 8, 9, 15-18, 36, 37 and 46 will still be pending and under examination.

The Claimed Invention

This invention provides a method of inhibiting atherosclerosis in a subject suffering from hyperlipidemia which comprises administering to the subject a polypeptide comprising the amino acid sequence of soluble receptor for advanced glycation endproduct (sRAGE) or a derivative thereof capable of inhibiting an interaction between amyloid- β peptide and receptor for advanced glycation endproduct (RAGE) in an amount effective to inhibit atherosclerosis in the subject.

March 9, 2004 Advisory Action

On March 9, 2004, the Examiner issued an Advisory Action stating that applicants' February 12, 2004 Amendment had not overcome the rejections made in the November 12, 2003 Final Office Action.

July 15, 2004 Examiner's Interview

On July 15, 2004, applicants' undersigned attorney, Alan J. Morrison, Esq. had a telephonic interview with Supervisory Patent Examiner Brenda Brumback and Examiner Ruixiang Li concerning the Advisory Action. Applicants wish to thank the Examiners for their

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time and consideration during the interview.

According to the Examiners during the July 15, 2003 interview, applicants would obviate the outstanding novelty rejection were they to demonstrate that the instantly claimed invention is adequately supported under 35 U.S.C. §112 by priority application U.S. Serial No. 08/592,070 ("070 application") and as a result entitled to an effective filing date of January 26, 1996, which is the filing date of the '070 application.' This support would be shown if it were demonstrated that all the elements of the claimed invention, including the amino acid sequence of sRAGE, are disclosed in the '070 application.

Applicants maintain that such support has been demonstrated herein, and that accordingly, the pending rejections have been overcome. In this regard, applicants reminded the Examiners that enablement under 35 U.S.C. §112, first paragraph, has been conceded regarding the subject application. (See May 7, 2003 Office Action (Paper No. 32) at 3).

Claim of Priority

The Examiner asserts that the subject matter defined in claims 1-4, 8, 9, 15-18, 36, 37 and 46 has an effective filing date of August 5, 1997, which is the filing date of the subject application. The 08/592,070 application ("070 application"), filed on January 26, 1996, allegedly fails to provide adequate support under 35 U.S.C. §112 for the instantly claimed invention.

Applicants respectfully traverse the Examiner's position regarding

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applicants' claim of priority with respect to claims 1-4, 8, 9, 15-18, 36, 37 and 46.

These claims, as discussed above, provide a method of inhibiting atherosclerosis in a subject suffering from hyperlipidemia which comprises administering to the subject a polypeptide comprising the amino acid sequence of soluble receptor for advanced glycation endproduct (sRAGE) or a derivative thereof capable of inhibiting an interaction between amyloid- β peptide and receptor for advanced glycation endproduct (RAGE) in an amount effective to inhibit atherosclerosis in the subject.

The test for enablement under 35 U.S.C. §112, first paragraph, is whether the disclosure contains sufficient information regarding the subject matter of the claims to enable one skilled in the relevant art to practice the claimed invention without undue experimentation.

Again, as stated by Supervisory Examiner Brumback during the July 15, 2004 interview, the '070 application will be deemed to provide adequate support under 35 U.S.C. §112 for the instantly claimed invention if applicants can demonstrate that all the elements of the claimed invention, including the amino acid sequence of sRAGE, are disclosed in the '070 application.

Applicants maintain that the '070 application discloses all of the elements of the claimed invention including the amino acid sequence of sRAGE. The Examiner, on page 3 of the November 12, 2003 Final Office Action, concedes that the '070 application discloses a method for treating a subject with hyperlipidemic atherosclerosis

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by administering an agent capable of inhibiting the interaction of amyloid- β peptide with RAGE at page 13, lines 21-35. The Examiner, also on page 3 of the Final Office Action, further concedes that the '070 application discloses the use of sRAGE as the agent in the method at page 11, lines 27-28. Lastly, the '070 application discloses the amino acid sequence of the extracellular domain of RAGE which corresponds to sRAGE at page 29, line 26 and page 30, lines 1-5 and 14-15.

Accordingly, applicants maintain that the '070 Application provides adequate support under 35 U.S.C. §112 for the subject matter of claims 1-4, 8, 9, 15-18, 36, 37 and 46, as amended. As a result, the subject matter of claims 1-4, 8, 9, 15-18, 36, 37 and 46 is entitled to an effective filing date of January 26, 1996, which is the filing date of the '070 application.

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1-4, 8, 9, 15-18, 36, 37 and 46 under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Specifically, the Examiner asserted that the definition for the amino acid sequence of sRAGE in the '070 application is ambiguous, because there is no sequence identifier provided for the amino acid sequence of sRAGE in claim 1.

In response, applicants respectfully traverse this rejection. Applicants maintain that there is no ambiguity as to the amino acid sequence of sRAGE in the '070 application. The '070 application clearly identifies the amino acid sequence of sRAGE as the 30-35kDa band listed in Table 1. Page 29, line 26; page 30, lines 1-5 and

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14-15. As a result, no sequence identifier is required for claim 1.

In view of the above remarks, applicants maintain that claims 1-4, 8, 9, 15-18, 36, 37 and 46 satisfy the requirements of 35 U.S.C. §112, second paragraph.

Rejection Under 35 U.S.C. §102(e)

The Examiner rejected claims 1-4, 8, 9, 15-18, 36, 37 and 46 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 5,864,018 ("Morser").

In response, applicants respectfully traverse this rejection.

A rejection based on 35 U.S.C. §102(e) can be overcome by perfecting priority under 35 U.S.C. §120 by amending the specification of the application to contain a specific reference to a prior application. Applicants contend that the claimed invention is entitled to a priority date of January 26, 1996 as discussed above. Therefore, since Morser is only available as a reference as of August 16, 1996, i.e. after the January 26, 1996 effective filing date of the claimed invention, Morser is not available as a §102(e) reference.

In view of the above remarks, applicants maintain that claims 1-4, 8, 9, 15-18, 36, 37 and 46 satisfy the requirements of 35 U.S.C. §102(e).

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Summary

For the reasons set forth hereinabove, applicants respectfully request that all the claims of this application be allowed, and that the application proceed to issuance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the \$55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being transmitted this date by facsimile and is addressed to: Mail Stop AF; Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Alan J. Morrison
Reg. No. 37,399

Date

8/17/04

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